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PEREZ v. WYETH LABORATORIES INC.
& THE WISDOM OF AN
ADVERTISING EXCEPTION TO
THE LEARNED INTERMEDIARY RULE

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The Perez Decision

On August 9, 1999, the Supreme Court of New Jersey issued the first high-level court opinion to recognize a direct-to-consumer (“DTC”) advertising exception to the learned intermediary rule.¹ Although the manufacturer in Perez v. Wyeth Lab. Inc. had satisfied its duty to provide medical professionals with full warnings, the court held that the usual protection offered by the learned intermediary rule was not automatically available since the manufacturer had engaged in DTC advertising. Because the manufacturer’s advertising campaign on television and in women’s magazines had failed to warn of certain

¹Perez v. Wyeth Laboratories Inc., 734 A.2d 1245 (N.J. 1999).

side effects and complications attendant to removal of its Norplant implants, the court held that the question of whether inadequate warnings constituted proximate cause should be submitted to a jury.

The 5-2 majority relied on a novel understanding of the learned intermediary rule to justify its exception. It suggested that since the learned intermediary rule was announced in a Norman Rockwell setting where physicians still made house calls, the shift to managed care had rendered the rule less appropriate.²The majority also employed great creativity in locating the so-called premises of the learned intermediary doctrine in: (1) a reluctance to undermine the doctor-patient relationship; (2) an absence in the era of “doctor knows best” of the need for the patient’s informed consent; (3) the inability of the drug manufacturer to communicate with patients; and (4) the complexity of the subject.³This unique characterization of the rule enabled the majority to declare these four premises invalid in the context of DTC advertising and therefore to find the learned intermediary rule inapplicable in this context.

The majority’s holding was truly extraordinary in light of the plaintiffs’ express failure to allege that they had been influenced by Norplant DTC advertising.

The court noted as much⁴but arrogated to itself the issue of whether DTC ad-

²See *id.* at 1255.

³See *id.* at 1255. For a discussion of traditionally stated rationales of the learned intermediary rule, see *infra* notes 32 to 39 and accompanying text.

⁴See *id.* at 1263-1264 (“We have no doubt that substantial proofs will be marshaled to show that Norplant is a safe and efficacious product and that Wyeth’s advertising, if any, was fairly balanced. An agreed statement of facts submitted to the trial court suggested as much.”).

vertising might have served as a proximate cause of the plaintiffs' injuries.⁵ Based on three chief assertions – (a) that DTC prescription drug advertisements may cause pushy patients to press, wheedle, beg, and berate physicians for a prescription, (b) that financially strapped physicians cannot afford to lose patients in the age of managed care, and (c) that physicians cannot compete with DTC advertising budgets so they will eventually relent to pressure⁶– the court concluded that DTC advertising may be sufficient to constitute a proximate cause of harm. It further held that where a manufacturer has advertised directly to the consumer, the prescribing physician may not break the chain of causation for a manufacturer's failure to warn the patient of side effects. Because the majority was reluctant to excuse a physician entirely from liability for an inappropriate prescribing decision, however, it held that a manufacturer held liable might seek contribution.⁷ In an interesting twist on the opinion, the court announced that a rebuttable presumption exists where a manufacturer has satisfied its duty to warn end-users by complying with FDA advertising, labeling, and warning requirements. It stated that "FDA regulations are pertinent in determining the nature and extent of any duty of care that should be imposed on pharmaceutical manufacturers with respect to direct-to-consumer advertising,"⁸ appearing almost to create a private right of action for failure to

⁵See id. at 1260.

⁶See id. at 1261.

⁷See id. at 1263.

⁸See id at 1259.

comply with FDA requirements.⁹ However, it added that because FDA-approved advertising is “fair and balanced...[for] all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims. By definition, the advertising will have been ‘fairly balanced.’”¹⁰ With these instructions, it remanded the case to the lower court to determine whether Norplant’s advertisements violated FDA requirements and whether such violations were a substantial factor in causing the harm suffered by the plaintiffs.¹¹ A dissenting judge offered a particularly withering assessment of the majority’s newly-recognized advertising exception. He observed that the majority was only able to reach its holding by ignoring the plain statutory language that codified the state legislature’s endorsement of the learned intermediary doctrine.¹² Noting the majority’s willful mischaracterization of the duty to warn the physician as one based on manufacturers’ formerly circumscribed advertising activities, he asserted that the rule’s more universal premise is that physicians are the actors best situated to make an individualized determination of the drug’s risks.¹³ He was particularly critical of the majority’s selection of Norplant as a the vehicle for advancing an advertising exception, noting that the significant involvement

⁹See Arvin Maskin, Konrad L. Cailteux and Lynda R. Vescio, *Manufacturer-to-Patient Advertising: Further Advice Following Perez*, 18 No. 7 Prod. Liab. L. & Strategy 5 (2000).

¹⁰See Perez, 734 A.2d at 1259.

¹¹See *id.* at 1262.

¹²See *id.* at 1265.

¹³See *id.* at 1266.

of a healthcare provider is assured in the case of Norplant because it requires surgical implantation, cannot not be purchased anonymously in a supermarket or over the internet, and is not promoted by HMOs.¹⁴ Unexplained assertions pervade the first opinion to recognize a DTC advertising exception to the learned intermediary rule. For instance, the majority seized on the more active role patients play under managed care to recharacterize the physician's role as essentially ministerial in the drug prescribing process, without explaining precisely how more actively involved patients invalidate the role of the physician as ultimate gate-keeper to the receipt of prescription drugs.¹⁵ The majority similarly disposed of a highly controverted issue in stating that the mere act of advertising to consumers has eliminated a timeless difficulty of conveying detailed medical information in a meaningful way to laymen without further elaboration of why this was so.¹⁶ The majority provided no justification for collapsing the distinctions between failure to inform and actively misleading to "misrepresenting," so as to impose a fraudulent-misrepresentation analysis on a failure-to-warn claim.¹⁷ These notable inadequacies in reasoning as well as the

¹⁴See id. at 1268.

¹⁵See id. at 1256 ("The fact that manufacturers are advertising their drugs and devices to consumers suggests that consumers are active participants in their health care decisions, invalidating the concept that it is the doctor, not the patient, who decides whether a drug or device should be used").

¹⁶See id. at 1256 ("Consumer-directed advertising rebuts the notion that prescription drugs and devices and their potential adverse effects are too complex to be effectively communicated to lay consumers").

¹⁷See id. at 1264 ("We are certain that legislative codification of the learned intermediary doctrine - which generally relieves a pharmaceutical manufacturer of an independent duty to warn the ultimate user of prescription drugs, as long as it has supplied the physician with information about a drug's dangerous propensities - does not confer on pharmaceutical manufacturers a license to mislead or deceive consumers when those manufacturers elect to exercise their right to advertise their product directly to consumers."). See also Maskin et. al., *supra* note 12.

novelty of the majority's new-found exception give pause to reexamine the evolution of the learned intermediary rule and the wisdom of establishing a DTC advertising exception.

Evolution of the Learned Intermediary Rule

Pharmaceutical manufacturer liability has long been a unique area of products liability law. Generally a manufacturer of an unreasonably dangerous product is held strictly liable for a harm that results, but most jurisdictions adhering to this standard have exempted prescription drug manufacturers from it. The exemption is premised on the notion that although prescription drugs are by their very nature incapable of being made safe for ordinary and intended use, the public benefits from the availability of these drugs.¹⁸ Thus, in liability suits concerning a prescription drug manufacturer's failure to provide adequate warnings, liability is usually determined through a negligence-based reasonableness inquiry,¹⁹ with the inquiry focused on the adequacy of the warnings and

¹⁸See Restatement (Second) of Torts section 402A cmt. k (1965) (which has been adopted by a majority of jurisdictions and which exempts prescription drug manufacturers from strict liability). Comment K, in relevant part, reads:

Unavoidable Unsafe Products. There are some products which in the present state of human knowledge are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The seller of [prescription drugs, vaccines, and the like] products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held in strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

¹⁹See Tim S. Hall, Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Consumer Prescription Drug Advertising, 2 Cornell J.L. & Pub. Pol'y 449, 457-458 (1993) ("Because the uncertainty of much drug design, and the fact that even a designer may not know for certain how a drug works (and the inability of a designer to substitute a less dangerous alternative), courts traditionally have not applied defective design

the parties to whom warnings should be issued. Courts have long held that a prescription drug manufacturer's common law duty to warn of a drug's dangerous propensities is limited to members of the medical profession who stand between the manufacturer and the end-user. This conception of the duty to warn is known as the learned intermediary rule, which holds that full warnings to the medical community excuse the manufacturer from a common law duty to warn directly the end-users of its drug.²⁰ The term "learned intermediary" was first coined by the Eighth Circuit in Sterling Drug, Inc. v. Cornish,²¹ a case concerning the manufacturer's failure to warn end-users of a rare side effect of its arthritis drug. In its decision, the court announced that a prescription drug manufacturer discharges its duty to warn the ultimate users of its drug by providing the medical profession with full warnings that elaborate on the known or reasonably foreseeable risks associated with the prescription drug.²² It reasoned that the physician, upon receipt of full warnings associated with the drug, was the most strategically situated actor to prevent injury to the consumer.²³ In the years immediately following, virtually all jurisdictions to consider the issue analysis to prescription drugs").

²⁰See, e. g., Chambers v. G.D. Searle & Co., 567 F.2d 269 (4th Cir. 1977) (applying Maryland law); Givens v. Lederle, 556 F.2d 1341 (5th Cir. 1977) (applying Florida law); Dalke v. Upjohn Co., 555 F.2d 245 (9th Cir. 1977) (applying Washington law); Salmon v. Park Davis & Co., 520 F.2d 1359 (4th Cir. 1975) (applying North Carolina law); McCue v. Norwich Pharmacal Co., 453 F.2d 1033 (1st Cir. 1972) (applying New Hampshire law); Terhune v. A.H. Robbins Co., 577 P.2d 975 (1978).

²¹370 F.2d 82, 85 (8th Cir. 1966).

²²See id. (where the court noted that this was because it was dealing with a prescription drug rather than a normal consumer item and because "the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer").

²³See id. ("If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided").

found the learned intermediary rule applicable in failure-to-warn cases involving prescription drugs.²⁴ Case law in its aftermath have defined the rule's parameters. The learned intermediary rule has been extended to imply no duty to warn end-users even where the manufacturer is aware that physicians are not warning those end-users of known side effects of a prescription drug.²⁵ The duty to warn extends, however, to all physicians who are involved with a patient in a "decision-making capacity."²⁶ Adequacy is satisfied only if a manufacturer discloses any warnings the manufacturer knows or should know are associated with the drug²⁷ and notifies the medical profession of any subsequent adverse effects discovered to be associated with the drug.²⁸ The learned intermediary rule functions as an affirmative defense and is usually asserted as a summary judgment motion in a failure-to-warn case. If the defendant manufacturer is able to demonstrate that it supplied the medical profession with adequate information about the drug's risks and benefits, its duty to warn the patient of risks attendant to the drug has been discharged.²⁹ In such cases, proximate cause may still

²⁴57 A.L.R. 5th Section 2(a).

²⁵See Buckner v. Allergan Pharm. Inc., 400 So.2d 820, 824 (Fla. Dist. Ct. App 1981), review denied, 407 So.2d 1102 (Fla. 1981) ("Since physicians do not have an absolute duty to inform patients of all possible side effects in every instance, failure to do so in a particular instance should not give rise to a duty in the manufacturer.").

²⁶See McEwen v. Ortho Pharm. Corp., 528 P.2d 522, 529 (Or. 1974).

²⁷See Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 381 (D. Md. 1975), aff'd, 567 F.2d 269 (4th Cir. 1977).

²⁸See Lindway v. Ortho Pharm. Corp., 637 F.2d 85, 91 (2nd Cir. 1980).

²⁹See, e.g., Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 811 (5th Cir. 1992); Abbot v. American Cyanamid Co., 844 F.2d 1108, 1115 (4th Cir. 1988); Plummer v. Lederle Lab., 819 F.2d 349, 356 (2d Cir. 1987); Stone v. Smith, Kline & French Lab., 731 F.2d 1575, 1579 (11th Cir. 1984); Wyeth Lab., Inc. v. Fortenberry, 530 So.2d 688, 691 (Miss. 1988); Niemiera v. Schneider, 555 A.2d 1112, 1117 (N.J. 1989); Martin v. Hacker, 628 N.E.2d 1308, 1311 (N.Y. 1988).

be attributed to the physician for failure to evaluate and communicate pertinent warnings supplied by the manufacturer. Traditionally the rule has shielded manufacturers from liability in failure-to-warn suits, regardless of the source of information received by the consumer before taking the drug.³⁰ This is largely because plaintiffs encounter difficulty getting the question of adequacy of the physician's warning to the jury.³¹ The learned intermediary rule is premised on several different but mostly congruent rationales. First, it is rooted in the notion that the physician is best situated to understand the complex benefit and risk information because of his or her education.³² Ancillary to this belief is that it is difficult, if not impossible, for manufacturers to communicate complex and technical risk information directly to the average reasonable person in a comprehensible, meaningful manner;³³ hence, responsibility for conveying that

³⁰See Joseph P. McMenamin, Samuel L. Tarry Jr. and Dennis J. Whelan, *How Perez v. Wyeth Laboratories Will Affect Direct-to-Consumer Drug Advertising*, 18 No. 5 Prod. Liab. L. & Strategy 7 (1999). But see Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 Ga. L. Rev. 141, 160 (1997) (noting that the adequacy of warnings provided to physicians may be undermined by failing to include known risk information, failing to draw sufficient attention to warning information, diluting the strength of warnings by overpromoting the product to the physician, or not communicating the warnings through the most effective means available).

³¹See Noah, *supra* note 30, at 159-160 ("Although physicians may have an incentive to shift blame to the drug manufacturer, normally they will testify that they understood the warnings provided by the manufacturer, as contrasted with a plaintiff's testimony that the warning communicated to the physician seemed insufficient.").

³²See *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1276 (5th Cir. 1974) (containing the widely quoted justification for the learned intermediary doctrine of "Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a learned intermediary between manufacturer and consumer.").

³³See *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984) (noting that direct warnings to end-users would be "almost inevitably involved and long winded" and "not...in

warning is allocated to the learned intermediary, who stands between the manufacturer and ultimate consumer as the most appropriately situated to disclose warnings of a drug's particular side effects and contraindications.³⁴ Further, the rule assumes that a manufacturer is unable to communicate an individualized risk assessment to each end-user but that learned intermediary is situated to do so. It is expected that the physician will make use of his or her understanding of the drug's benefits, side effects, and contraindications to perform an individualized benefit-risk analysis that takes into account a patient's particular needs and susceptibilities before deciding to prescribe a drug. Additionally, the rule reflects the belief that the physician's ability to communicate individualized risk information is superior to that of the manufacturer, as he or she may sense that a patient requires further explanation and may answer patient follow-up questions.³⁵ Other controverted rationales of the rule are that provision of warnings directly to consumers will interfere with the physician-patient relationship,³⁶ may actually endanger the patient's health,³⁷ and are inappropriate to the patient's best interest"). See also Noah, *supra* note 30, at 159 ("because of the complexity of risk information about prescription drugs, comprehension problems would complicate any effort by manufacturers to translate physician labeling for lay patients").

³⁴See Lars Noah, *supra* note 30, at 158 ("Drug manufacturers lack effective means to communicate directly with patients, making it necessary to rely on physicians to convey the relevant information.").

³⁵See Barbara Pope Flannagan, *Products Liability: The Continued Viability of the Learned Intermediary Rule as it Applies to Product Warnings for Prescription Drugs*, 20 U.Rich. L. Rev. 405, 413 (1986) ("The physician can articulate a warning to a patient, answering any questions which the patient might have. In addition, the physician can recognize a patient who might need more explanation. The physician is usually more accessible for follow-up questions. In other words, no matter how well the drug manufacturer may predict the circumstances under which the consumer may need to be warned regarding risks, the physician's warning is superior.").

³⁶See Noah, *supra* note 30, at 157 (cataloguing rationales of the learned intermediary rule).

³⁷See generally McKee v. American Home Prods. Corp., 782 P.2d 1045, 1055 (Wash. 1989)

because the physician should be the sole source of information about prescription drugs.³⁸ These particular rationales are premised on the somewhat controversial (and arguably discredited) paternalistic model of the physician-patient relationship and they do not explain why the rule is an optimal allocation of the responsibility to warn the end-user. They do not necessarily assume that the physician is the only strategic actor able to make full use of manufacturer warnings but only that the paternalistic model of a physician-patient relationship is worth preserving and that the rule is helpful in maintaining that hierarchy by preserving the physician as the sole source of risk information. These rationales, however, are heavily relied upon by those seeking to invalidate the premises of the learned intermediary rule.³⁹ In limited instances where courts have found the rationales of the learned intermediary rule particularly weak with respect to a class of prescription drugs, they have recognized an exception to the rule requiring the manufacturer to warn the end-user directly. These exceptions recognized fall principally into three categories: mass vaccinations, drugs with FDA-mandated consumer warnings, and contraceptives.

The only exception widely recognized by a majority of courts falls in the area (“package inserts, written for the physician, are detailed and technical, and may confuse and frighten the patient”). This justification appears to be a slight variation on non-interference with the physician-patient relationship rationale, rooted in the assumption that warnings may frighten a patient to the point of causing him or her to discontinue the drug-therapy without informing the physician.

³⁸See Teresa Moran Schwartz, Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule, 46 Food Drug Cosm. L.J. 829, 842 (1991). It is doubtful whether the physician has ever served as the sole source of information (see *infra* notes 130 to 138 and surrounding text) and arguably serves more as an manufactured basis on which to topple the learned intermediary rule rather than a truly descriptive basis of the rule.

³⁹A prime example of this is the Perez majority’s emphasis on the loss of the Norman Rockwell physician in recognizing a DTC advertising exception.

of mass immunizations.⁴⁰ Courts have located an exception where there is no physician present to perform an individualized benefit-risk assessment for each patient administered the vaccine.⁴¹ Thus, where physicians serve only in an administrative oversight role and are not acting as learned intermediaries in advising patients individually, the manufacturer’s duty to warn of side effects extends to the actual recipients of the vaccine.⁴² This exception for mass immunizations has since been largely undercut by the National Childhood Injury Compensation Act,⁴³ which establishes a no-fault compensation scheme for those injured by vaccinations. Fueled by a national vaccine crisis in the 1980s, the no-fault compensation scheme insulates manufacturers from liability by eliminating any tort claims based on a manufacturer’s failure to provide direct warnings to injured individuals.⁴⁴ Congress ultimately withdrew the issue of end-user warnings from the province of the courts in this area, because open-ended tort liability

⁴⁰See, e.g., Mazur v. Merck & Co., 964 F.2d 1348, 1361-64 (3d Cir. 1992); Petty v. U.S., 740 F.2d 1428, 1440 (8th Cir. 1984).

⁴¹See, e.g., Davis v. Wyeth Labs, 399 F.2d 121, 131 (9th Cir. 1968) (determining that the duty to warn end-users of a vaccine did not create an unreasonable burden because it could be accomplished by provided stated warning on a release form); Reyes v. Wyeth Labs, 498 F.2d 1264, 1276-1277 (5th Cir. 1974) (finding that defendant manufacturer had duty to warn individual recipients of vaccine when the product is “dispensed without the sort of individualized medical balancing of the risks of the vaccinee that is contemplated by the prescription drug exception”); Givens v. Lederle Labs, 556 F.2d 1341 (5th Cir. 1977) (finding an exception even where the vaccine was administered in a physician’s office).

⁴²See, e.g., Davis, 399 F.2d at 131.

⁴³National Childhood Vaccine Injury Act of 1986, 42 U.S.C. section 300aa-14(a)(Supp. II 1990) (establishing a no-fault recovery system).

⁴⁴See Charles J. Walsh, Steven R. Rowland & Howard L. Dorfman, The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling, 48 Rutger L. Rev. 821, 861-862 (1996). See also Craig A. Marvinney, How Courts Interpret a Manufacturer’s Communications to Consumers: The Learned Intermediary Doctrine, 47 Food & Drug L.J. 69, 72 (1992) (arguing that this exception has led to some unanticipated consequences, including the fact that “the exodus of manufacturers of these products over the last twenty years has rendered the United States almost without manufacturers of vaccine drugs”).

failed to protect individuals and dramatically raised the cost of a product beneficial to the public at large.⁴⁵ A handful of courts have also suggested that the learned intermediary rule may not automatically shield drug manufacturers from liability where the FDA requires direct warnings to end-users.⁴⁶ The only case to hold, however, that FDA-mandated direct warnings alone justifies an exception to the rule is Edwards v. Basel Pharmaceuticals.⁴⁷ In this opinion, the Supreme Court of Oklahoma held that the rule did not shield a manufacturer from liability in a wrongful death action stemming from overuse of a prescription nicotine patch. In the abbreviated patient warning accompanying the product, the manufacturer had failed to advise of the possibility of fatal or cardiac-related reactions to nicotine overdose, even though the manufacturer had fully warned the prescribing physician of its side effects.⁴⁸ The court held that the FDA regulations requiring nicotine patch manufacturers to provide certain warnings to end-users rendered the learned intermediary defense unavailable in a failure-to-warn claim.⁴⁹ It further held that compliance with an FDA mandate was evidence that a manufacturer acted reasonably and satisfied a minimum standard but was not an absolute defense to a liability claim.⁵⁰ Other

⁴⁵See Walsh et al., supra note 44, at 862.

⁴⁶See, e.g. MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65 (Mass. 1985), cert. denied, 474 U.S. 920 (1985); Stephens v. G.D. Searle, 602 F. Supp. 379 (E.D. Mich. 1985); Odgers v. Ortho Pharmaceutical Corp., 609 F. Supp. 867 (E.D. Mich. 1985); Lukaszewicz v. Ortho Pharm. Corp., 510 F. Supp. 961 (E.D. Wis. 1981), amended by 532 F. Supp. 211 (E.D. Wisc.); Hill v. Searle Lab., 884 F.2d 1064 (8th Cir. 1989).

⁴⁷933 P.2d 298 (Okla. 1997).

⁴⁸See id. at 301.

⁴⁹See id.

⁵⁰See id. at 302.

courts, when confronted with the opportunity to recognize an exception where FDA has mandated warnings, have held that FDA regulations do not change preexisting state common law duties of manufacturers.⁵¹ A few of courts have also broached the possibility of an exception to the rule for prescription contraceptives,⁵² although the overwhelming number of courts have applied the learned intermediary rule in such cases. MacDonald v. Ortho Pharmaceutical Corp.⁵³ is the only case holding unequivocally that there is an exception for contraceptives. In this case, the Supreme Judicial Court Massachusetts held that it was not reasonable for a manufacturer to rely on a learned intermediary to convey adequate warnings to the end-user⁵⁴ and it let stand the jury decision that the manufacturer's failure to warn end-users directly of the risk of a stroke proximately caused the plaintiff's injury.⁵⁵ The court justified its exception on the belief that oral contraceptives "bear peculiar characteristics which warrant the imposition of a common law duty on the manufacturer to warn users directly of associated risks."⁵⁶ It supported this contention on three principal assertions:

⁵¹See, e.g., Martin v. Ortho Pharmaceutical Corp., 661 N.E.2d 352 (Ill. 1996); Lacy v. G.D. Searle & Co., 567 A.2d 398 (Del. 1989); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293 (D. Minn. 1988); Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1033 (D.N.J. 1988); Goodson v. Searle Lab., 471 F. Supp. 546 (D. Conn. 1978).

⁵²See, e.g., Hill v. Searle Lab., 884 F.2d 1064, 1071 (8th Cir. 1989); Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867, 878 (E.D. Mich. 1985); Stephens v. G.D. Searle, 602 F. Supp. 379 (E.D. Mich. 1985).

⁵³475 N.E.2d 65 (Mass. 1985).

⁵⁴See id. at 70.

⁵⁵See id. at 72.

⁵⁶See id. at 69.

(1) that healthy individuals' active participation in the decision to use prescription oral contraceptives relegates physicians to a relatively passive role; (2) that oral communications between physicians and consumers may be insufficient or too infrequent to fully apprise consumers of the product's dangers at the time of initial selection and subsequent renewal; and (3) that FDA regulations require manufacturers to furnish consumers with written information regarding benefits and risks.⁵⁷ Such a blanket exception has not been adopted outside the state of Massachusetts in the 15 years following the opinion's release, as courts confronted with the issue have rejected the "passive physician" rationale advanced by the MacDonald court.⁵⁸ While the duty to warn end-users directly in the case of mass immunizations is easily rationalized on grounds that the learned intermediary rule assumes and requires the direct involvement of a learned intermediary, the rationales underlying the FDA-warning and contraceptive exceptions are far less compelling. In both cases, the learned intermediary plays a vital and undiminished link in the end-user's receipt of the prescription drug. A medical professional must make an individualized determination as to whether the a prescription is appropriate as well as determine the proper

⁵⁷See *id.*

⁵⁸See, e.g. In re Norplant Contraceptive Prods. Liab. Litig., 165 F.3d 374 (5th Cir. 1999); Martin v. Ortho Pharm. Corp., 661 N.E.2d 352, 356 (Ill. 1996); West v. Searle & Co., 806 S.W.2d 608, 614 (Ark. 1991); Reaves v. Ortho Pharmaceutical Corp., 765 F. Supp. 1287, 1291 (E.D. Mich. 1991); Taurino v. Ellen, 579 A.2d 925 (Pa. Super. Ct. 1990); Flumes v. Clinton, 792 P.2d 1032, 1039 (Kan. 1990); Allen v. G.D. Searle & Co., 708 F.Supp. 1142 (D. Or. 1989); Lacy v. G.D. Searle & Co., 567 A.2d 398 (Del.1989); Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1032 (D. N.J. 1988); Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1305 (D. Minn. 1988); Stafford v. Nipp, 502 So.2d 702, 704 (Ala. 1987); Rhoto v. Ribando, 504 So.2d 1119, 1123 (La. App. 1987); Eiser v. Feldman, 507 N.Y.S.2d 386, 387 (N.Y. App. 1986).

type and dosage of the prescription drugs in question before an individual can legally obtain them. In the case of FDA-mandated warnings, comprehensive labeling requirements are a tribute to the seriousness of potential side effects and are not aimed to affect the standard of civil tort liability.⁵⁹ Similarly, in the case of contraceptives, the elective versus nonelective distinction trumpeted is not meaningful and wholly irrelevant in terms of the vital role played by the learned intermediary. Further, the plus factor emphasized in connection with the non-therapeutic distinction – the infrequent checkups associated with use of the drug – does not undercut the rationale of the intermediary rule but rather bespeaks the importance of the initial prescribing decision.⁶⁰ The irrelevance of these distinctions is recognized by most courts, who have squarely rejected the opportunity to recognize exceptions for drugs carrying FDA-mandated warnings and prescription contraceptives.

Perez’s Potential Reach in Light of Previously Recognized Exceptions

There are several reasons to expect that the Perez opinion may not ignite a widespread advertising exception in light of this history of the learned intermediary rule. Most importantly, Perez is not a secure opinion in the sense that it is the product of strong lineage. Opinions that lay the groundwork for recognizing an advertising exception were scant. Only one court before Perez suggested in a footnote that DTC promotion alone may influence a manufacturer’s duty to warn end-users directly, and the opinion was reversed on other grounds on ap-

⁵⁹See Walsh et al., *supra* note 44, at 867.

⁶⁰See *id.*

peal.⁶¹ Additionally, only two other precursor opinions made a passing reference to DTC advertising⁶² in focusing on the peculiar class of prescription contraceptives. The duty to warn end-users imposed by the courts in both instances hinged on the non-therapeutic nature of the drug and DTC promotion as a potential factor influencing such a duty was relegated to dictum. Moreover, these three cases were outlier opinions among the much larger group of opinions squarely rejecting an exception for DTC advertising.⁶³ Favorable case precedent for recognizing a DTC advertising exception clearly eluded the Perez majority, as evident in its almost exclusive reliance on law review articles.

Perez's most immediate precursor decision also suggests a limited significance of the opinion. In re Norplant Contraceptive Prods. Liab. Litig.,^{64a} a 5th Circuit opinion that predated the Perez decision by only several months and that also dealt with Norplant, explicitly rejected an advertising exception. In affirming the trial court's grant of summary judgment to the manufacturer, the Fifth

⁶¹See Garside v. Osco Drug, Inc., 764 F.Supp. 208, 211 n.4 (D. Mass 1991), rev'd 976 F.2d 77 (1st Cir. 1992) (where the court suggested in dicta that in "an appropriate case, the advertising of a prescription drug to the consuming public may constitute a third exception to the learned intermediary rule").

⁶²See Hill v. Searle Labs., 884 F.2d 1064, 1066 (8th Cir. 1989) (where the court determined that comment K covered only critically needed prescription drugs and not the non-therapeutic intrauterine device in question); Stephens v. G.D. Searle & Co., 602 F. Supp. 379 (E.D. Mich. 1985) (finding that a manufacturer is under a duty to warn patients directly of the side effects of contraceptives when prescribed for contraceptive purposes).

⁶³See, e.g., Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806 (5th Cir. 1992); Hunt v. Hoffman-LaRoche, Inc., 785 F.Supp. 547 (D. Md. 1992); Bealer v. Hoffman-LaRoche, Inc., 729 F. Supp. 43 (E.D. La. 1990); Harwell v. American Med. Sys. Inc., 803 F. Supp. 1287 (M.D. Tenn. 1992); Hufft v. Horowitz, 5 Cal. Rptr. 2d 377 (Ct. App. 1992); Ramey v. Collagen Corp., 821 S.W.2d 208 (Tex. Ct. App. 1991).

⁶⁴165 F. 3d 374, 379 (5th Cir. 1999).

Circuit rejected the plaintiffs' claim that the Texas Deceptive Trade Practices Act superseded the learned intermediary rule and held that the learned intermediary rule is a rule of law rather than a common law defense.⁶⁵ The court rejected the plaintiff's invitation to recognize an advertising exception based on the manufacturer's aggressive marketing practices, observing that there was no evidence in the record supporting the claim that the plaintiffs relied on marketing materials.⁶⁶ It held, moreover, that even if there were evidence of reliance on promotional material the only germane issue to determining applicability of the learned intermediary rule would be whether the drug was dispensed by a physician.⁶⁷ The court also noted that FDA-recommended warnings did not defeat the learned intermediary rule, holding that the rule applied in full force where the severity of potential side effects caused the FDA to promote additional labeling.⁶⁸

It remains unclear, however, what role the Restatement (Third) of Torts will play in future litigation where plaintiffs urge a DTC advertising exception. Section 6 of the most recent edition approved by the American Law Institute provides a set of ground rules for imposing liability on pharmaceutical manufacturers where the drug is allegedly defect due to inadequate warnings or instructions. Preliminary drafts of the edition sought to recognize several exceptions to the learned intermediary rule, including where FDA mandates consumer warnings and where a manufacturer engages in DTC advertising, but

⁶⁵See *id.* at 378.

⁶⁶See *id.* at 379.

⁶⁷See *id.*

⁶⁸See *id.*

these proposals were eventually dropped⁶⁹ and the final draft took no position on the issue.

Nonetheless, the final version adopted contains two ambiguities that state courts with an agenda may attempt to exploit in recognizing an advertising exception. Subsection 6(d)(2) states that manufacturer liability attaches where the manufacturer knows or has reason to know that no health care provider will be in a position to reduce risks in accordance with its warnings and where the manufacturer fails to communicate warnings directly to the patient.⁷⁰ This was presumably aimed at mass immunizations where a physician-patient relationship does not exist, but it may provide an opportunity for plaintiff lawyers to argue that managed care relationships fall within its ambit. Comment e notes that direct advertising of prescription drugs is a relatively recent development and thus “leaves to developing case law” the issue of whether exceptions to the learned intermediary rule ought to be recognized where (a) the manufacturer engaged in DTC promotion or (b) FDA regulations mandated direct warnings for end-users.⁷¹ It is unquestionable that plaintiffs will attempt to use this open-ended language to persuade courts to recognize a DTC advertising exception to the learned intermediary doctrine.⁷² The Perez plaintiffs did precisely this, and

⁶⁹See Restatement (Third) of Torts: Products Liability section 103(a)(3)(iii)(Council Draft Do. 1, 1993). As noted in Noah, *supra* note 30, at 164-166, the accompanying notes to this draft failed to cite any case law directly supporting an advertisement exception and cited only one law professor’s article urging such an exception.

⁷⁰Restatement (Third) of Torts: Products Liability section 6(d)(2)(1997).

⁷¹Restatement (Third) of Torts: Products Liability Cmt. 3 at p. 155. See also Jeffrey A. Cohen and Janet A. Sullivan, Gray Areas Exist in Restatement (Third) on Drugs, Medical Devices, 17 No. 3 Prod. Liab. L. & Strategy 1 (Sept 1998).

⁷²See Bob Van Voris, “Drug Ad Could Spell Legal Trouble: Consumer Campaigns May Result in Greater Liability,” Nat’l L.J., July 21, 1997 at B1.

the majority relied upon the Restatement (Third) of Torts' opening in creating its DTC advertising exception. It remains to be seen whether other courts will choose to construe the Restatement's commentary in a similar fashion in resolving failure-to-warn cases.⁷³ However, the Restatement's noncommittal approach to an advertising exception leaves unanswered the questions of (1) whether an exception is the appropriate response to the proliferation of DTC advertising and (2) whether it would mark a positive direction for "developing case law."

The Rise of DTC Advertising

The exact proportions of DTC prescription drug advertising, as described by the Perez majority, bear mention in examining what impact, if any, it ought to play in altering existing tort liability of manufacturers.

Promotion of prescription drugs directly to consumers is a relatively recent development of the past two decades. Previously, manufacturers restricted promotional efforts to physicians, concentrating their efforts on print advertisements in medical journals and direct pitches to physicians. In 1983, however, the first television ad for a prescription drug appeared. FDA responded immediately with a regulatory letter⁷⁴ and shortly thereafter with a "Statement of Policy" requesting the suspension of such advertisements so that the agency might study the issue. After an ample period of time in which to consider DTC advertising

⁷³See Noah, *supra* note 30, at 144 (commenting that "the Reporters ultimately succeeded at including language that may lead courts to expand greatly the duty of drug manufacturers to warn consumers of prescription drug risks, especially when combined with the FDA's proposed new regulations").

⁷⁴See "Rx Advertising to Consumers," FDA Talk Paper No. T83-23, May 23, 1983.

of prescription drugs, FDA lifted its moratorium and permitted pharmaceutical manufacturers to continue DTC prescription drug advertising under the regulatory safeguards then in place in 1985.⁷⁵

Prescription drug advertisements have since become commonplace in newspapers, magazines, and television advertisements. Over the years manufacturers have branched out from “informative” advertisements, which lack the name of the manufacturer’s drug prescribed to treat the featured condition, to advertisements that are product specific.⁷⁶The Rogaine promotional campaign marked the first of the ever-popular product specific advertisements⁷⁷and product specific advertisements occupy a prominent position in manufacturers’ promotional campaigns today.

DTC advertising of prescription drugs has soared in the past two decades and the upward trajectory shows no signs of leveling. DTC prescription drug advertising is currently the sixth largest category of consumer advertising in the U.S., with an estimated value at 1.8 billion.⁷⁸In the first half of 1999 alone, DTC expenditures for prescription drugs reached \$905 million, a 43 percent increase over spending for the same period the previous year.⁷⁹Use of DTC advertising

⁷⁵See Peter Barton Hutt and Richard A. Merrill, Food and Drug Law 465 (2nd ed. 1991).

⁷⁶See Hall, *supra* note 19, at 452.

⁷⁷But see *id.* at n.9 (commenting that the line separating purely informative from product-specific was somewhat hazy as “some ads that appeared prior to the Rogaine campaign were criticized for crossing the line between information and product-specific selling”).

⁷⁸See “Just a Spoonful of Sugar,” *Australasian Business Intelligence: Marketing Magazine*, March 1, 2000.

⁷⁹See Matthew R. Miller, “US Spends \$905 Million on DTC Prescription Drug Advertising,” *Response TV*, November 1, 1999, p. 19 (citing London-based IMS Health).

as a promotional tool also appears to be widely embraced by prescription drug manufacturers: in the first 10 months of 1999, manufacturers launched 22 new DTC campaigns to advertise brand-name drugs and 10 campaigns to highlight diseases.⁸⁰ These numbers are accompanied by a rise in consumers reporting exposure to a prescription drug advertisement.⁸¹ As of 1999, television advertisement appeared to be the favored DTC advertising medium of choice. For the first half of the year, manufacturers spent \$529 million on television, \$370 million on print advertising, and \$4.7 million on radio and outdoor advertising.⁸² The steady surge in DTC prescription drug advertising expenditures has been propelled by the lure of greater profits. Studies measuring the effectiveness of such advertising are limited, although they indicate that DTC has been a success from the manufacturer's point of view in terms of raising awareness of a particular drug. A study tracking DTC since 1988 concludes that DTC advertising campaigns are a powerful tool in terms of raising consumer awareness of available treatment options, encouraging patients to schedule physician visits, and encouraging patients to request specific medications by name.⁸³ Results of the study also suggest that DTC advertisements have played a substantial role in facilitating dialogue between patients and physicians.⁸⁴ Raw numbers from

⁸⁰See "Scott-Levin Releases Year in Review 1999," Business Wire, March 24, 2000.

⁸¹See "DTC-Generated Rx Script Volume Remains Flat," The Pink Sheet, October 4, 1999 ("As of April 1999, 81% of adult consumers had seen or heard an ad for an Rx medication, an 11% jump from the 70% reported in 1998, and a significant rise from the 63% reported in 1997.").

⁸²See Miller, *supra* note 79.

⁸³See Tom Marcinko, Medical Marketing & Media (November 1, 1998).

⁸⁴See *id.* ("three-quarters of the physicians surveyed in 1996 (the most recent year for which

the past year also support this proposition: of the 176.7 million consumers who had viewed DTC advertisements for prescription drugs, 54.8 million discussed advertised drugs with their physicians, and 15.3 million requested a prescription based on an advertisement, 12.9 million of which received that prescription.⁸⁵ Three-fifths of medical conditions accounting for increased physician visits were conditions featured in DTC ad campaigns.⁸⁶ Further, drug sales surged in pharmaceutical categories most heavily advertised to consumers over the past year.⁸⁷ The relationship between aggressive DTC advertising and sales may not be as linear as critics suggest, however, for several reasons. Although the rate of patients that visit physicians is strong among consumers who are aware of DTC advertising,⁸⁸ the rate of recall is much lower among mature consumers who are the target audience most likely to use prescription drugs.⁸⁹ Further, most consumers viewing DTC advertisements remain unaware of the specific health condition that an advertised drug is targeted to treat after exposure to promotional activities.⁹⁰ Additionally, patient requests for a specific drug based

these data are available), said that patients had talked about the contents of DTC ads they had heard or seen”).

⁸⁵See “Awareness of Direct-to-Consumer Prescription Drug Ads Stalls,” Research Alert, Vol 17 Issue 19, October 1, 1999 (citing a Prevention Magazine survey).

⁸⁶See Marcinko, *supra* note 83.

⁸⁷See Jill Wechsler, “The DTC Dilemma,” *Pharmaceutical Executive*, November 1, 1999 (citing the PE Washington Report of September 1999 stating that oral antihistamines, antidepressants, cholesterol-reducers, and antiulcerants led the drug sales surge).

⁸⁸See Christine Truelove, “Creativity is Creeping in DTC,” *Med Ad News*, November 1, 1999, p. 1 (citing a study conducted by Market Measures Inc.).

⁸⁹See *supra* note 85.

⁹⁰See *id.*

on DTC advertising do not automatically result in a prescription for that drug and often times results in a prescription for a competitor product.⁹¹ Profiles of the relationship between DTC advertising expenditures and sales for individual prescription drugs also refute the notion that there is a direct correlation. For instance, Pfizer's aggressive DTC promotion of Viagra has yielded disappointing results for its manufacturer, as its DTC campaign has proved insufficient to sustain the sales even after taking into account the expected slowdown in sales post initial excitement.⁹² Thus, while manufacturers engaging in DTC advertising have enjoyed gains, the correlation between promotion and prescriptions appears to be more complicated than the direct correlation touted by advertising critics.

The FDA's Response to DTC Advertising

The FDA's current regulation of DTC advertising is another critical component in assessing the necessity and desirability of altering manufacturer liability through recognition of an advertising exception.

FDA currently regulates advertisements pursuant to its prescription drug authority under 21 U.S.C.A. 352(n) of the Food, Drug and Cosmetic Act. The FDA retains the authority to monitor DTC advertising materials and may sanc-

⁹¹See "One-Third of Consumers Ignore DTC Print Ad Brief Summary," The Green Sheet, January 31, 2000. In analyzing the results of the FDA's survey "Attitudes and Behaviors Associated With Direct-to-Consumer Promotion of Prescription Drugs," it notes that "many Rx requests instigated by a DTC campaign are being fulfilled by competitor products, the survey found. Of the 220 consumers who had asked about a prescription in the three months prior to the survey, 50% received a prescription in the three months prior to the survey, 50% received a prescription for that product, 32% received a different Rx, 14% were recommended an OTC treatment and 29% were given lifestyle change recommendations."

⁹²See "Weak Sales of Viagra Hurt Pfizer's Results," Medical Industry Today, October 15, 1998.

tion errant manufacturers by the usual methods of (a) sending an untitled letter stating the FDA's objections to the promotional material, (b) issuing a warning letter asking the manufacturer to discontinue the advertisement or take remedial measures, (c) seizing or enjoining the use of materials making similar claims, or (d) criminally prosecuting the manufacturer and individuals involved.⁹³ FDA has also requested authority to enforce civil monetary penalties "in an amount sufficient to offset any potential gains from the violative conduct," which if granted by Congress, will further strengthen the agency's ability to enforce its DTC guidance.⁹⁴ Enforcement of the FDA's guidelines in the realm of prescription drug DTC advertising is not officially accomplished at the preclearance of advertisements stage,⁹⁵ although the FDA encourages "voluntary" preclearance of such advertisements. In practice, however, preclearance is the de facto course of action for manufacturers because they cannot afford to ignore the request in light of their ongoing relationship with the FDA. Further, preclearance enables these manufacturers to avoid formal reprimand by the FDA and the bad publicity that ensues.⁹⁶ FDA's surveillance efforts in the realm of DTC advertising are also bolstered by consumer groups and by competitor drug companies who are spurred by heightened competition to point out inadequacies of

⁹³Direct-to-Consumer Promotion, 61 Fed. Reg. 24,314, 24, 315 (1997).

⁹⁴See 56 F-D-C Rep., "The Pink Sheet," Oct. 17, 1994 at 6.

⁹⁵21 C.F.R. Section 202.1(e)(1) (although manufacturers must seek preclearance if the drug in question may cause fatalities or serious injury).

⁹⁶See Tamar V. Terzian, Direct-to-Consumer Prescription Drug Advertising, Am. J.L. & Med. 149, n. 133 (1999) ("If, however, a pharmaceutical company submits a new promotion through the DDMAC's optional preclearance process, objections to an advertisement will be conveyed privately, thus sparing the company from bad publicity.").

their opponents' broadcasts.⁹⁷ DTC advertisements of prescription drugs are subject to the brief summary requirement,⁹⁸ which requires advertisements to include a "brief summary relating to side effects, contraindications, and effectiveness."⁹⁹ An advertisement lacking a brief summary and fair balance is deemed by the FDA to be misleading or false and ultimately misbranded.¹⁰⁰ Although the brief summary requirement typically requires inclusion of all package insert information, the FDA has recognized that the length of broadcast advertisements render the disclosure of full labeling impossible and that insistence on the regular brief summary would eliminate the use of broadcast advertising. Thus, it has formulated special rules to accommodate radio, television, and telephone DTC advertising. These special rules obligate a sponsor to make a "major statement" of major risks and side effects in the broadcast advertisement but permit the sponsor to make "adequate provision" for the package labeling in connection with the presentation if the brief summary is not part of the broadcast.¹⁰¹ Prior to 1997, the requirements for satisfying adequate provision in

⁹⁷See Greg Borzo, "New FDA Rules for Advertising Drugs on TV Raises Questions," *Am. Med. News*, Sept. 8, 1997, at 3. See also Terzian, *supra* note 96, at 164.

⁹⁸Note, however, that reminder ads (which feature the medication and manufacturer's names but no claims about the drug's effectiveness) and help-seeking ads (which urge consumers to consult with a physician about certain conditions) are exempt from the brief summary requirement because they avoid substantive remarks about a particular prescription drug.

⁹⁹21 C.F.R. Section 202.1(e).

¹⁰⁰21 C.F.R. Section 202.1(e)(5)(1997). The FDA construes this liberally to "include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems."

¹⁰¹21 U.S.C. Sec. 202.1(e)(1). See also Karl E. Seib, Jr. and Andrew E. Miller, *Courts Should Rebuff Assault on 'Learned Intermediary' Rule*, 1 No. 7 *Andrews Diet Drugs Litig. Rep.* 18.

DTC prescription drug advertising were somewhat indeterminate. In an effort to enable manufacturers to fulfill DTC advertising requirements, the FDA released a Draft Guidance in August of that year establishing a four-part test for adequate provision in broadcast advertisement.¹⁰² It instructed sponsors to: (1) feature a toll-free phone number at which consumer may request package insert information; (2) inform viewers that additional product information is available in print advertisements or brochures; (3) state that pharmacists or physicians may provide additional product information; and (4) feature a web address in the advertisement or toll-free phone recording.¹⁰³ The response by industry to the Draft Guidance has been overwhelmingly positive, as the guidance has been credited with spawning the biggest spending increase in the history of pharmaceutical advertising. Because the guidelines considerably eased the burden on manufacturers engaging in broadcast promotion by clarifying regulatory requirements, the guidelines cleared the way for a majority of pharmaceutical manufacturers to diversify their promotional efforts from mostly print advertisements to radio and television advertisements.¹⁰⁴ The guidance also appears to have influenced manufacturers' selection of the media type for such campaigns,

¹⁰²62 Fed. Reg. 14,912, 14,913-16 (1997). Note that the Draft Guidance is not legally binding and does not establish legally enforceable rights or responsibilities. However, FDA's practice has been to issue technically non-binding policy statements and guidance so as to avoid cumbersome formal rulemaking procedures which grant interested parties a right to demand a hearing. See Noah, *supra* note 30, at 146 ("after originally promulgating its advertising regulations in the 1960s, the Agency has preferred to issue technically nonbinding policy statements and guidelines...or to pursue individualized enforcement actions in this area.").

¹⁰³See "Consumer-Directed Broadcast Advertisements," *The Pink Sheet*, Vol. 59, No. 32, p. 4 (August 11, 1997).

¹⁰⁴See Joseph P. McMenamin, Samuel L. Tarry Jr. and Dennis J. Whelan, Pulling the Net From Beneath Consumer-Directed Advertising, 18 No. 4 *Prod. Liab. L. & Strategy* 1 (Oct. 1999).

as DTC advertising on television has climbed dramatically.¹⁰⁵ The FDA has proved adept at monitoring compliance with the guidance and detecting attempts to flout its basic requirements. In the year following the announcement of the 1997 guidelines, the FDA detected violations in recalling more than 10 ads that it believed to overstate benefits and concomitantly understate risks.¹⁰⁶ In particular, the FDA demonstrated competence in singling out manufacturers who attempted to gloss over side effects through background music, distracting visuals, and increasing the rate of voice-over copy¹⁰⁷ and in swiftly securing redress of violations.¹⁰⁸ Further, in reviewing the guidelines two years after their initial release, FDA demonstrated a responsiveness to DTC advertising concerns that developed and a willingness to tailor changes to these concerns by incorporating six changes to the guidance.¹⁰⁹ The guidelines have operated

¹⁰⁵See Marcinko, *supra* note 83 (reporting that the use of television in DTC promotion rose from 21% in 1996 to 47% in the first quarter of 1998, whereas magazine use fell from 71% to 47% in the same time period).

¹⁰⁶See "Direct to Consumer Ads: FDA Rules Create Ad Bonanza," *American Health Line*, August 10, 1998.

¹⁰⁷See Laurie Freeman, "Accepting the Risks: Throng of Possible Side Effects Go Hand in Hand With Creative to Meet FDA Guidelines," *Advertising Age*, April 3, 2000 (citing Roche as reprimanded by the FDA "when ads for fat-blocker Xenical...used distracting music to drown its list of gastrointestinal and other side effects").

¹⁰⁸See Terzian, *supra* note 96, at 153 (chronicling the FDA's reprimand of Schering-Plough for reading side effects so quickly in two of its Claritin advertisements that it was difficult for consumers to understand, where television networks pulled the ads immediately and Schering-Plough quickly revised the ads to comply with guidelines).

¹⁰⁹See CDER "Consumer-Directed Broadcast Advertisements Guidance" Commentary, August 1999. The changes include: (1) reformatting the assumptions underlying what constitutes a compliant broadcast advertisement in general; (2) deleting the option under the toll-free telephone component of the adequate provision approach to offer to fax product labeling to consumers; (3) emphasizing the need for the print advertisement component of the adequate provision approach to be broadly disseminated; (4) acknowledging that the print brochures alternative component of the adequate provision approach was likely to be feasible only when broadcasting was fairly limited in scope; (5) acknowledging explicitly that health care professionals other than physicians and pharmacists can be sources of additional human drug product information; and (6) adding a discussion to clarify the differences in satisfactory adequate provision approaches for telephone advertisements, compared with television or radio

as a flexible tool, capable of responding to developments in DTC advertising and abuses. The FDA remains committed to surveiling developments in DTC advertising, studying such developments, and counteracting problems by instituting changes in its guidelines where necessary. In finalizing its draft guidance, the FDA communicated its growing impatience to advertisers who satisfy the adequate provision requirement for broadcast ads by disseminating the drug's brief summary in an obscure manner and announced its intention to monitor the availability of print advertisements.¹¹⁰ The FDA also signaled that it may reconsider adequate provision disclosure guidance that permits broadcast ads to feature such disclosures while reading risk information simultaneously, in order to combat low consumer recall of disclosures identifying print and web pages as sources of additional information.¹¹¹ Additionally, it has commissioned a survey to analyze the effects of prescription drug advertising on consumers.¹¹² Lastly, the FDA is examining the effect of increased DTC advertising on public health over the next two years and is prepared to fine-tune its guidance further if necessary.¹¹³ The agency has not taken its responsibility to protect consumers in the realm of DTC advertising lightly and there is no reason to expect that it advertisements.

¹¹⁰See id. ("FDA generally believes that a sponsor has not provided adequate access to the product's package labeling when the print component of their adequate provision approach is highly targeted or made only narrowly available and the product is broadly advertised in broadcast media.").

¹¹¹See James G. Dickinson, "Most Recent DTC Developments Favor Print Over Broadcast Media," *Medical Marketing & Media*, September 1999.

¹¹²63 Fed. Register 49,582 (1998).

¹¹³See Wechsler, *supra* note 87.

will shirk its responsibility to do so in the future.

Although FDA is currently entrusted with the task of regulating prescription drug advertising, a shift in responsibility to the FTC remains a possibility. Some have argued that as advertisements become more sophisticated, the FTC may be better suited than the FDA to regulate such advertising.¹¹⁴ They note that the transition in authority would be relatively smooth, as the FTC currently has jurisdiction over OTC drug advertisements. There is ample support for continued FDA authority in this area, however. As regulatory authority is currently structured, FDA is able to leverage its power in product approvals to exert great influence on wayward manufacturers who have engaged in advertising violations particularly when the manufacturers have product approvals pending before the FDA. Swift corrective action is likely to follow an FDA reprimand under such circumstances, because if a company's financial backers suspect that resistance to an FDA enforcement policy might delay a pending drug approval, the company's market value and financial stability may be jeopardized.¹¹⁵ Further, the FDA's emphasis on a more vigilant and hands-on regulatory style may be better suited to grapple immediately with advertising abuses in contrast to FTC's reliance on self-regulation and private resolution of disputes.¹¹⁶ Based on the FDA's demonstrated vigilance in the area of DTC prescription drug advertising abuses and current incentives for manufacturers to comply with FDA-recommended

¹¹⁴See Terzian, *supra* note 96, at 154.

¹¹⁵John F. Kamp, CDER Direct-to-Consumer Promotion Hearing, October 18, 1995.

¹¹⁶See Terzian, *supra* note 96, at 155.

alterations, the FDA appears competent to monitor DTC advertising. Because there is little reason to believe that the FDA will become complacent and fail to fine-tune guidelines in response to future problems that are identified, the assertion that a DTC advertising exception is a necessary blunt instrument to counteract advertising abuses is unsupported.

Criticisms Levelled at DTC Advertising/Reasons Advanced for Creating an Advertising E

There are those that argue that an advertising exception is necessary to supplement to current FDA regulations, however. At a general level, they highlight that the chief goal of DTC prescription drug advertising is to promote the use and sale of a product rather than to educate the consumer.¹¹⁷ They assert that DTC marketing is geared towards forming “consumer preferences” and increasing demand for inappropriate medication which will ultimately result in an increase of end-user injuries¹¹⁸ and therefore weaken the underpinnings of the learned intermediary doctrine.¹¹⁹ They argue that increased sales of prescription drugs in the age of DTC advertising reflect not only past underutilization of a

¹¹⁷See Hall, *supra* note 19, at 462 (arguing that only FDA regulation and enhanced manufacturer liability through an advertising exception together “will prevent blatant puffery and insupportable claims of efficacy without destroying the character of the advertising”).

¹¹⁸See Barbara J. Tyler and Robert A. Cooper, *Blinded by the Hype: The Burden When Manufacturers Engage in Direct to Consumer Advertising of Prescription Drugs*, 21 Vt. L. Rev. 1073, 1098 (1997) (citing *Prescription Drug Advertising Direct to the Consumer*, 88 Pediatrics 174, 175 (1991) for this proposition). The causal connection between “consumer preferences” and increased end-user injuries implied here seems to hint at the harm of self-medication. Self-diagnosis and medication by prescription drugs is rendered an impossibility under the prescription/OTC classification regime because a health care professional’s approval is a necessary prerequisite, but this distinction is glossed over by those asserting that consumer injuries are a direct result of DTC advertising.

¹¹⁹See Hall, *supra* note 19, at 461 (where the author asserts a classic argument of this type in stating that DTC “clearly influences the balance of power in the physician-patient relationship. A physician confronted with a patient who is informed about the treatment alternatives will probably give substantial weight to that patient’s desires when making treatment decisions.”).

drug therapy but inappropriate use of medications that have resulted in monetary and human costs. Based on these assumed adverse effects,¹²⁰ they argue that an advertising exception is necessary.

The rationales on which they mount this claim fall primarily into 4 categories.

The Hobbled Intermediary Rationale

Advertising exception proponents' strongest theory on which to base the exception is a hobbled intermediary. Advocates of an advertising exception allege that a manufacturer's DTC promotion efforts should not be shielded by the learned intermediary doctrine because the effect of such promotion is to bypass the learned intermediary altogether.¹²¹ They argue that DTC advertising undermines a physician's ability to function as a medical care provider, therefore causing the physician to grant inappropriate requests for prescription drugs.¹²² They note that the prospect of inappropriate prescriptions is heightened in an age where patients may "doctor shop" or receive prescriptions from physicians on the internet by answering a series of questions and forgoing a physical examination.¹²³ Because manufacturers advertise prescription

¹²⁰There are those that impute far less savory motivation to DTC advertising exception proponents, however. See, e.g. Noah, *supra* note 30, at 170 ("Ultimately, although they elaborate on the supposed weakness for rationales for the learned intermediary rule in cases where manufacturers advertise directly to consumers, proponents of an advertising exception seem to rest their position on what they perceive as crass, profit-motivated advertising of prescription drugs. Once pharmaceutical manufacturers stoop to direct consumer advertising, the argument goes, they no longer deserve the special treatment that they have enjoyed under tort law.").

¹²¹See, e.g., Schwartz, *supra* note 38, at 848 ("Once they engage in such advertising, they become like any other product seller and the same product liability rules should apply. There is no justification for protective rules that shield drug manufacturers from direct responsibility to the consumer.").

¹²²See Seib, Jr. et al, *supra* note 101.

¹²³Note that these specific injuries are the direct result of questionable physician practices rather than the learned intermediary rule as it currently functions in an age of DTC prescription

drugs directly to consumers, these advertising exception proponents argue that these manufacturers assume the obligation to warn consumers directly and disprove the idea that it is too difficult to provide meaningful consumer warnings.¹²⁴ Further, they claim that an exception is necessary to force manufacturers to internalize the costs incidental to an advertising campaign,¹²⁵ which they allege are quite high in lieu of manufacturers' manipulation of consumer risk assessment.¹²⁶ They anticipate that the creation of an exception will reverse drug manufacturers' unwillingness to include user-friendly warnings that might refute the claims of the promotional material and will ensure that the public receives risk information necessary to properly weigh manufacturers' promotional claims.¹²⁷ **Informed Consent Rationale**

Proponents of an advertising exception sometimes argue from an informed consent perspective as well. Under the doctrine of informed consent, a physician

drug advertising. Additionally, these injuries do not occur at the behest of manufacturers, because manufacturers oppose on-line sales to first time users and are actively fighting them. Bad medical practices are better addressed by state medical boards and by amending federal law, which currently only requires that doctors either have a relationship with the patient or a consultation "during the usual course of his professional practice." For a lengthier discussion of this problem, which is beyond the scope of this paper, see Louis Lavelle, "Growth of On-line Pharmacies Raises Concern/Doctors, State Consider Them Bad Medicine," *The Record*, December 6, 1998 p. A1.

¹²⁴See, e.g., Schwartz, *supra* note 41, at 842-843 ("The proposition that prescription products are too complex, and individual reactions too varied, to permit effective consumer warnings may also be difficult for manufacturers to argue, because their current advertisements do carry warnings.").

¹²⁵See Tyler and Cooper, *supra* note 121, at 1096.

¹²⁶See *id.* at 1095 ("The marketing gimmick used by the drug manufacturer often provides the consumer with a diluted variation of the risks associated with the drug product.").

¹²⁷See *id.*, at 1096. See also Susan A. Casey, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 *Wm. Mitchell L. Rev.* 931, 956 (1993) ("consumer-directed advertising rebuts the notion that prescription drugs and devices and their potential adverse effects are too complex to be effectively communicated to lay consumers").

may be held liable for failing to communicate pertinent risks and therefore failing to obtain the patient's informed consent before pursuing a course of treatment. Advertising exception proponents argue that the standard for informed consent - one traditionally informed by local practice of the medical community - does not adequately convey information to patients in practice and is inconsistent with a patient's right to self-determination.¹²⁸ The argument appears to be that both the physician and manufacturer are capable of disclosing this information, and that manufacturers should be required to do so in case physicians fail to do so. A DTC advertising exception in this context functions as a convenient peg upon which to hang a critique of the current informed consent standards and thus is designed to ensure that a patient will receive full disclosure by circumventing the discretion of the physician.

What remains unclear under this theory is why a physician's failure to satisfy his legal obligation to supply warning information implicates DTC advertising sponsored by prescription drug manufacturers as opposed to standards by which informed consent is measured. Informed consent attacks ultimately do not challenge the basic premises underlying the intermediary rule¹²⁹ and fail to present a cogent argument why responsibility for a physician's failure to comply with

¹²⁸See Schwartz, *supra* note 38, at 831. See also Casey, *supra* note 27, at 958. It is not clear why this supports an advertising exception rather than the inclusion of PPIs in drugs dispensed. See *infra* notes 182 to 187 and accompanying text.

¹²⁹See *Buckner v. Allergan Pharm. Inc.*, 400 So.2d 820, 824 (Fla. Dist. Ct. App 1981), review denied, 407 So.2d 1102 (Fla. 1981) (where the court rejected the notion that standards of informed consent may render the learned intermediary rule unavailable, noting that "since physicians do not have an absolute duty to inform patients of all possible side effects in every instance, failure to do so in a particular instance should not give rise to a duty in the manufacturer.").

legal obligations should devolve to manufacturers in the form of heightened tort liability.

Interference in the Patient-Physician Relationship

Another theory attacks DTC advertising from the opposite angle, arguing that an exception is necessary because the information supplied by DTC advertising disrupts the doctor-patient relationship as it formerly functioned.¹³⁰ This critique is rooted in a paternalistic, if not somewhat antiquated, conception of the optimal doctor-patient relationship where the patient plays a deferential role in making major medical decisions.¹³¹ The weaknesses with respect to this rationale are facially apparent. It is unclear why a physician's irritation at a patient's DTC advertisement-inspired questions should factor prominently into the analysis of whether DTC advertising merits an exception to the learned intermediary rule. In fact, there is a strong argument to be made that increasing patient involvement in health care in the form of inquiry about suitable treatment is a welcome change that should be encouraged rather than quashed by heightening manufacturer liability for advertising. Further, there is a certain inconsistency in rooting an exception which would essentially mandate full consumer warnings on a noninterference rationale, as the exception would institute

¹³⁰See e.g., Hall, *supra* note 19, at 450 ("the doctor will find it commensurately harder to educate patients with preconceived expectations about a treatment gained from direct-to-consumer advertisements").

¹³¹Note that the evils of paternalism have also been used to denounce the continued existence of the learned intermediary doctrine. See, e.g., Casey, *supra* note 127, at 958. While these critiques quite rightly note that it is paternalistic to presume a layperson incapable of digesting warnings, it is arguably paternalistic only in the sense that it shifts full responsibility to learned intermediaries to comprehend the warnings. The rule does not bar or seek to discourage laypersons from seeking out warning information on their own and thus is a much less attenuated form of paternalism.

only a different type interference in terms of heightened patient anxiety and potential distrust of physicians who failed to mention all of the contraindications individually.

Even assuming that limiting the participation of patients in healthcare decisions was a worthy goal, it is not clear that curbing DTC advertisements through heightened manufacturer liability would tackle the problem of increasingly informed patients. Those arguing for a DTC advertising exception on an interference rationale conveniently ignore that it is one of but several influences that “interferes” with a physician/patient relationship. It is not clear that the physician-patient relationship has ever been completely walled off from outside interference but this notion is increasingly contradicted by the widespread availability of information on prescription drugs.

Several information sources independent of DTC advertising may play a prominent role in an individual’s decision to initiate conversation about a particular prescription drug with a physician. There are numerous written information sources available to patients, including counseling sheets often distributed with drugs purchased at a pharmacy, the Physician’s Desk Reference, and many websites. These may be supplemented by more informal sources, such as the rave reviews of well-intentioned family members, friends, or other third parties currently benefiting from a prescription drug.¹³²

¹³²See Julie Zito, CDER Direct-to-Consumer Promotion Public Hearing, October 18, 1995.

Limiting the information to which consumers have access so as to avoid burdensome questioning for physicians does not appear to be a feasible option in this day and age, and an advertising exception will not ultimately halt the flow of information. The AMA has conceded this reality in abandoning its long-standing, unconditional opposition to DTC advertising¹³³ with the explicit caveat that the promotional material have educational value.¹³⁴ Moreover, an environment in which patients are more knowledgeable does not dictate that physicians will be demoted to a less active role in the decisionmaking process,¹³⁵ so the noninterference rationale does not really strike at the underpinnings of the learned intermediary rule.

Managed Care Rationale

Managed care is another rationale that features prominently in proposals for a DTC advertising exception. Proponents of an advertising exception assume

¹³³See Wendy Borow, CDER Direct-to-Consumer Promotion Public Hearing, October 19, 1995 (noting that when the AMA announced its new qualified support of DTC advertising, it stated that “this method of conveying health care information can serve as an excellent communication vehicle for alerting consumer to new therapeutic treatment modalities, encouraging people to seek medical advice for conditions that might otherwise go untreated, and enhancing the patient-physician relationship by increasing patient responsibility for healthy lifestyle and thus fostering increased dialogue between physician and patient.”)

¹³⁴See Hall, *supra* note 19, at n.4 (noting that in lifting its opposition to DTC advertising, the AMA provided two caveats: an advertisement must have “educational value” and drug manufacturers engaging in a DTC campaign must provide “physician education materials”).

¹³⁵See Noah, *supra* note 30, at 171 (“ethical and legal duties dictate that the physician retain an active role in the prescribing process, and consumer participation does not weaken those duties”). See also Catharine A. Paytach, *The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach to Preventing Drug-Related Injury*, 51 *Stan. L. Rev.* 1343, 1363 (“The fact that patients are more active in their health care decision does not render a physician inadequate. Indeed, informed and involved patients may only cause the physician to ponder prescription drug and therapy choices at greater length. In no way does this undermine the doctor’s knowledge or capability to assess drug treatment programs.”).

that the potential adverse effects of such advertising on consumers will be magnified in a managed care setting for several reasons. They note the doctors face increased pressure to reduce the length of patient visits. Similarly, they observe that patients are less likely to establish long-term relationships with the physician of their choice and more likely to suffer disruption in continuity of care due to the constraints managed care imposes.¹³⁶ They question whether physicians who are inundated with drug literature and struggle to maintain abreast of changes in medical knowledge will be able to stay informed of all of the hazards of drugs they prescribe.¹³⁷ From this they conclude that great familiarity with a patient's medical history will not serve as a protection against doctors capitulating to patient demand for an advertised drug. Although they are unable to marshal any empirical evidence to support these contentions, which the FDA has repeatedly pointed out,¹³⁸ these critics still argue that the manner in which medical services are provided furnishes a basis for an advertising exception to the learned intermediary defense.

¹³⁶The Perez majority employed this tactic in creating an advertising exception.

¹³⁷See Casey, *supra* note 127, at 957 (“Challenged by a constant bombardment of drug literature from manufacturers, the physician frequently is unable to keep up with the daily changes in the state of medical knowledge. The sheer volume of drug literature argues against the physician being informed of all the hazards of all the drugs and devices he or she prescribes.”) The chain of logic underlying this assertion is extremely weak, however. An age of information overload does not prove that the patient is better situated than a medical professional to evaluate the appropriateness of a prescription drug.

¹³⁸CDER Consumer-Directed Broadcast Advertisements Commentary, August 1999 (“FDA is unaware of any data supporting the assertion that the public health or animal health is being harmed, or is likely to be harmed, by the Agency's actions in facilitating consumer-directed broadcast advertising. FDA has repeatedly requested empirical data that would document the hypothesized effects - negative and positive - of DTC promotion on several factors related to public health. Despite years of print advertising, no rigorous evidence has been presented to demonstrate that DTC advertising has had any of the hypothesized ill effects.”).

A shift from a fee-for-service regime to managed care does not necessarily militate for an advertising exception, though. Physicians have an ethical and legal duty to prescribe medications that are not harmful to their patients, and the duty is not conditional on the length of the relationship or the method by which they are reimbursed.¹³⁹ Further, the assertion that physicians are overwhelmed with information to point of being unable to render proper judgment unless informed patients assist in analyzation¹⁴⁰ does not argue so much for an advertising exception than for an abandonment of prescription classification if its basis has been so thoroughly eviscerated by managed care.

Describing changes attendant to managed care does not equivocally support the advertising exception, moreover, as these changes can be just as easily marshaled to support and entrench DTC prescription drug advertising as a positive countervailing force. The rapid expansion of managed care may arguably support the use of such advertising for its informational properties. Advertisements that enable a patient to more accurately and specifically describe symptoms and to ask more pertinent, directed questions may serve an invaluable function in shorter, more impersonal patient visits.¹⁴¹ Further, DTC advertising may func-

¹³⁹See Paytash, *supra* note 135, at 1363 (noting that changes imposed by managed care do not imply “that a doctor who is not personally selected by a patient, who lacks a long-term professional relationship with that patient, and who bases his or her medical opinion solely on a health history, a physical examination, and a discussion with the patient cannot make an individualized medical judgment and prescribe an appropriate drug therapy regimen...It does not follow that because a more personalized doctor/patient relationship is preferable and ideal, that the lack of such a relationship renders medical decisions inadequate.”)

¹⁴⁰See *id.* at 1364.

¹⁴¹See Andrew S. Krulwich, CDER Direct-to-Consumer Promotion Public Hearing, Oct. 18, 1995.

tion as the only method of alerting patients to the existence of drug therapies not currently covered under a plan's formulary.¹⁴²In addition to educating plan enrollees, it may empower them to bargain for the addition of the drug to the restricted formulary and eventually create a groundswell protest that forces the plan to expand covered drug brands.¹⁴³It may also provide a patient with the knowledge needed to negotiate with a physician who operates in a system where the managed care organization has tied compensation to the prescription drug fund of that physician's patients and that refunds any money left in the fund at the year's end.¹⁴⁴Additionally, DTC promotion may provide a countervailing pressure to managed care organizations seeking to cut corners by helping to instill brand loyalty in end-users and thus assisting these end-users in fending off physicians' attempts to substitute generic versions even where the drug is on the formulary.¹⁴⁵Arguably, the provision of medical care in a managed care market where consumers are more informed by DTC prescription drug advertising secures a role for DTC advertising as a useful component of the present-day

¹⁴²See Terzian, *supra* note 96, at 158 ("Studies show that DTC advertising generates an increased patient load and often causes physicians to spend more time reviewing the benefits and risks of a specific brand with each patient and explaining formulary restrictions when patients request a brand that is outside the health plan's drug formulary.").

¹⁴³See "Direct to Consumer Ads: FDA Rules Create Ad Bonanza," American Health Line, August 10, 1998 ("Some consumer advocates are wary of HMOs and physicians who declare their opposition to DTC ads...[because] 'managed care companies wind up with nefarious deals with drug companies who lowball bids...(and) doctors don't complain about drug compan[ies] wining and dining them.'").

¹⁴⁴See Eugene Schonfeld, CDER Direct-to-Consumer Promotion Public Hearing, Oct. 18, 1995. Note that this stands in opposition to the Perez majority's assertion that managed care physicians seek to appease patients by providing inappropriate prescriptions because they cannot afford to lose patients.

¹⁴⁵See Noah, *supra* note 30, at 150. See also "Direct to Consumer Ads: FDA Rules Create Ad Bonanza," American Health Line, August 10, 1998 ("For HMO and other managed care companies, DTC ads create an additional demand for pricey pharmaceuticals.").

system rather than warranting an advertising exception.

Unheralded Benefits of DTC Advertising

Those prone to speculate on the magnitude of harm inflicted by DTC advertising of prescription drugs and the necessity of an advertising exception often fail to mention significant societal benefits that may accrue from such advertising. DTC advertising is a valuable tool precisely because it educates consumers¹⁴⁶ and disseminates information to a segment of people unreached by third-party education efforts and other public relation efforts. DTC advertising may also raise public awareness of stigmatized conditions and help to influence public perception for the better.¹⁴⁷ In particular, DTC advertising of prescription drugs may equip individual consumers with information that may help them take greater responsibility for their health care, particularly those not under the regular care of a physician.¹⁴⁸ For instance, it may convince them to seek out medical advice for symptoms they had not previously associated with serious medical conditions¹⁴⁹ or for medical conditions for which they were

¹⁴⁶Drug advertisements do not a substitute for medical advice and may be an incomplete sources of information, but this does not defeat the basic notion that they perform an information-providing function.

¹⁴⁷This is true, for instance, with respect to the DTC advertising campaigns for depression and impotence drugs. See Marcinko, *supra* note 83 (citing a psychologist's positive reaction to DTC advertising because "anything that decreases the stigma of mental illness and increases the number of people who get help is worth it").

¹⁴⁸See Karen Hanson, "Prescription Drugs Now Marketed Directly to Consumers," Copley News Service, March 20, 2000 (observing that many DTC ads target people who do not usually seek medical care, such as those struggling with weight loss, flu, or smoking cessation and motivate them to schedule a doctor appointment).

¹⁴⁹See "Awareness of Direct-to-Consumer Prescription Drug Ads Stalls," Research Alert, October 1, 1999 (noting that 24.7 million of 176.7 million viewers of DTC advertisements talked with physicians for the first time about allergies, heart disease, or diabetes as a direct result of these ads).

previously unaware that there was treatment.¹⁵⁰ This is particularly true with respect to newly available treatments because advertising may be an individual's first exposure to such treatments.¹⁵¹ It may also inform patients who were forced to discontinue a drug with intolerable side-effects of new treatment alternatives that lack those side effects.¹⁵² Even individuals under the regular care of a physician stand to benefit from the information provided by DTC prescription drug advertising. Such information may empower individuals to ask about symptoms a physician's questioning failed to bring to light and to describe symptoms with great specificity. It may also position a patient to benefit from the latest drug therapy where there is a lag in practice. For instance, it may prompt patients who currently take prescription drugs to inquire about a newer drug with less severe side effects and ensure that the switch occur more rapidly.¹⁵³ In serving a reminder function, DTC advertisements may also encourage patients under the care of a physician to comply with drug therapy and regular physician visits.¹⁵⁴ Substantial cost savings may result from DTC

¹⁵⁰See Terzian, *supra* note 96, at 166 ("Consumers with a chronic illness such as migraine headaches may not be aware of new drugs available to alleviate their pain; DTC drug advertisements can lead these people back to their doctors for relief."). See also Mary J. Sheffet, CDER Direct-to-Consumer Promotion Public Hearing, Oct. 18, 1995 (noting that with respect to the drugs Proscar or Hytrin, the condition being treated develops gradually, an individual may not be aware that the problem is coming and getting worse).

¹⁵¹See Hanson, *supra* note 148 (commenting that this is particularly true with respect to treatments for asthma, hypertension, diabetes, or influenza).

¹⁵²See Michael C. Allen, *Medicine Goes Madison Avenue: An Evaluation of the Effect of the Direct-to-Consumer Pharmaceutical Advertising on the Learned Intermediary Doctrine*, 20 Campbell L. Rev. 113, 128 (1997).

¹⁵³See Noah, *supra* note 30, at 150, citing to Yumiko Ono, "Drug Makers Try to Win Over Seldane Users," Wall St. J., Jan. 31, 1997, at B1 (commenting that this is likely to be most pronounced in advertising dogfights where competitors seeking to lure customers away from existing prescriptions).

¹⁵⁴See *id.* at 152.

prescription drug advertising. Where DTC advertising facilitates early recognition and intervention in medical conditions, it stands to improve public health and potentially reduce the costs of treating diseases.¹⁵⁵In the long run, DTC advertising of prescription drugs may also be expected to promote competition and encourage consumers to price shop, leading to an overall decline in the price of the drug.¹⁵⁶As manufacturers develop mass markets and are able to spread fixed costs of product development over a larger base of consumers and develop economies of scale in manufacturing, a downward trend in prices is likely to result.¹⁵⁷Thus, manufacturers' quest to increase name recognition and trigger patient-physician dialogue through DTC advertising stands poised to provide some public benefits.

Is Carving Out an Additional Exception the Appropriate Response to DTC Advertising?

In light of the magnitude of current DTC advertising expenditures for prescription drugs, the FDA's efforts to curb advertising excesses, and the potential costs and benefits that may redound from such advertising, what is the proper course of action? More specifically, ought consumer expectations informed by DTC advertising alter existing manufacturer liability in terms of

¹⁵⁵See Terzian, *supra* note 96, at 156.

¹⁵⁶See Alison Masson & Paul Rubin, "Matching Prescription Drugs & Consumers: The Benefit of Direct Advertising," 313 *New Eng. J. Med.* 513, 514 (1985) ("A number of empirical studies in other markets confirm that price decreases do sometimes occur when advertising is introduced into a market."); Eric P. Cohen, "Direct-to-the Public Advertisement of Prescription Drugs," 318 *New Eng. J. Med.* 373, 375 (1988) (citing an empirical study that found that states permitted advertising were found to have lower prescription drug prices).

¹⁵⁷See Schonfeld, *supra* note 144. However, others dispute this point and argue that when increased promotional costs are factored into the price, drug prices will perversely increase rather than decrease.

recognizing an advertising exception to the learned intermediary rule? Carving out such an exception in response to DTC advertising that fails to provide complete warnings would to be an asymmetrical & ill-advised response for several reasons.

The wisdom of eliminating the learned intermediary rule in this context is suspect. The theory that complete information about a particular prescription drug's side effects and contraindications may be effectively and adequately communicated because a manufacturer has engaged in DTC advertising is unproven,¹⁵⁸ as average consumers lack the requisite educational background to comprehend information. This assertion largely ignores the tradeoff that exists between clear, understandable (and hence meaningful) warnings and complete, legally adequate warnings for individuals without a medical background. Thus, requiring manufacturers to reduce complex warnings to a format understandable and legally adequate by individuals with no medical or scientific background is quite possibly a duty manufacturers are incapable of satisfying.¹⁵⁹ The notion that consumers can serve effectively as ultimate arbiters of prescription drug information if supplied with more complete information is also highly doubtful and unproven. Prescription drugs differ from other products advertised to the public in several critical aspects. By definition, they are considered inappropriate for consumer self-diagnosis and self-medication. This is based

¹⁵⁸Simply because a manufacturer has a large advertising budget and is able to communicate major warnings in a meaningful manner does not automatically mean that it may do the same respect to more complete (and complex) warnings. This is a difference that is largely ignored by those arguing that the act of advertising means that manufacturers are capable of conveying adequate warnings to consumers.

¹⁵⁹See Marvinney, *supra* note 44, at 73.

largely on the understanding that prescription drugs hold the potential for adverse effects that may not be easily conveyed due to medical complexity beyond an ordinary individual's comprehension.¹⁶⁰ Moreover, drug manufacturers lack the information necessary to tailor warnings to the specific heightened risks of a particular patient and therefore the ability to assist individual patients in determining the appropriateness of a prescription drug.¹⁶¹ Reshuffling responsibility from the physician, who is the most strategically situated to prevent consumer injury, to the manufacturer will not guarantee consumer protection. Detailed, technical layperson warnings will do little to protect those consumers who are adamant about obtaining the drug in particular.¹⁶² Expanding tort liability by removing the learned intermediary rule where a manufacturer has engaged in DTC advertising is not cost-free, moreover, and is likely to produce unintended results. Open-ended tort liability based on DTC advertising of a prescription drug may invite the results of the vaccine exception: compromised public health, individuals unprotected until they are injured and compensated *ex poste*, and a dramatic increase in the costs (and ultimately affordability) of drugs to offset the costs of increased liability.¹⁶³ Recognition of an advertising exception would

¹⁶⁰21 U.S.C. section 353(b)(1)(B) (stating that a drug must be dispensed by a physician when "its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a [licensed practitioner]").

¹⁶¹See Maskin et al, *supra* note 9. See also "Prescription Drug Advertising Direct to the Consumer," 88 *Pediatrics* 174, 175 (1991) (observing that proper judgment about a drug's suitability requires consideration of the patient's diagnosis, medical history, prior medications, adverse and allergic drug reactions, chemical dependency).

¹⁶²In particular, it will fail to protect the "doctor shoppers" and patients of internet physicians who disregard the reasoned judgment of medical professionals refusing to grant a prescription.

¹⁶³See Terzian, *supra* note 96, at 163 (noting that pharmaceutical companies may increase

subject manufacturers to a virtual land-mine of uncertainty, because current prescription drug warnings aimed at physicians would be unlikely to meet the legal standard of adequacy for a reasonable consumer.¹⁶⁴ This standard would be exacting if not impossible for manufacturers to satisfy.¹⁶⁵ Further, it would be one jury might often conclude was not met considering that many courts have created a rebuttable presumption of causal linkage in such cases.¹⁶⁶ An advertising exception would remove any predictability for manufacturers seeking to draft adequate warnings, as the common law is incapable of formulating tests that would enable manufacturers to reliably ascertain the adequacy of warnings in advance.¹⁶⁷ Submitting the issues of whether a warning was complete and understandable to a jury that may be swayed by unscrupulous “expert” witnesses would further magnify uncertainty and ratchet up potential liability for manufacturers.¹⁶⁸ Ultimately, manufacturers might respond to such expanded exposure of their prices to offset the costs of increased liability if the learned intermediary doctrine is set aside”).

¹⁶⁴MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65 (1985) is a prime example of this. In this case, the court noted that a “jury may have concluded...that the absence of a reference to ‘stroke’ in the [PPI] warning...failed to make the nature of the risk reasonably comprehensible to the average consumer,” even though the risk of someone suffering a stroke at the plaintiff’s age was 1.5 in 100,000.

¹⁶⁵See Flanagan, *supra* note 35, at 420 (observing that a what is reasonably comprehensible to the average consumer is an impractical and nebulous standard, dependent on variable jury determinations, and perhaps one that no warning would satisfy).

¹⁶⁶See Schwartz, *supra* note 38, at 847.

¹⁶⁷See Walsh, *supra* note 44, at 874.

¹⁶⁸See Marvinney, *supra* note 44, at 74. See also Noah, *supra* note 30 174-175 (“If courts recognized an advertising exception to the learned intermediary rule, then pharmaceutical manufacturers would have to find a way of disseminating patient package inserts, ensure that these inserts contained references to all possible side effects in nontechnical language, and in the unlikely event that they managed to design such an unassailable warning, hope that a jury would not decide that continued advertising to consumers diluted the effectiveness of that warning.”).

sure to liability by conveying less rather than more information to consumers in terms of curtailing their advertising campaigns¹⁶⁹ The solution proffered by the Perez court in terms of the use of compliance with FDA regulations as a rebuttable presumption does not entirely avoid these pitfalls. The presumption is not ironclad, so it would not reduce uncertainty for manufacturers altogether. Moreover, the use of FDA regulations to determine whether warnings to consumers were adequate is problematic because the regulations were not designed with that warning function in mind. As one commentator notes, “the FDA has not yet revised its advertising rules to require disclosures tailored to patients, and even if it does, the FDA has not designed its disclosure requirements to fulfill a warning function (in contrast to PPIs for oral contraceptives) so much as to ensure that promotional claims do not lack fair balance. Judicial review, in particular by juries, of whether the brief summaries appended to print advertisements adequately discharge any new-found duty to warn patients directly is bound to conclude that the warnings were inadequate for a purpose the FDA never had in mind.”¹⁷⁰ An advertising exception based on the hobbled intermediary theory would also leave unanswered the question of why the prescribing physician, who plays an indispensable function and who has not been demoted from the position of exercising ultimate judgment, may abdicate responsibility for determining a drug’s appropriateness and conveying risk information applicable to the individual patient.¹⁷¹ Further, it leaves unanswered why a physician

¹⁶⁹See Noah, *supra* note 30, at 169.

¹⁷⁰See *id.* at 176.

¹⁷¹The question remains unanswered as well in the literature urging the adoption of an

whose negligent prescription was not at an overbearing patient's behest should be sheltered by an advertising exception.¹⁷² The more compelling premise of the widely recognized exception for mass immunizations – an absent-learned intermediary – is absent in the case of prescription drugs, which by definition cannot be safely used by consumers absent the diagnosis and supervision of a physician. DTC advertising does not alter the role of physician as the ultimate gatekeeper because patients eager to try an advertised prescription drug cannot lawfully obtain the drug minus the assent of a physician. Shifting responsibility from the physician to the manufacturer simply because the manufacturer promoted a prescription drug directly to consumers makes little strategic sense if the chief concern is protecting patients *ex ante*, and it will not guard against the possibility that a patient may ingest a therapeutically inappropriate drug. Lowering the threshold of the standard of care to which a physician must adhere, in terms of engaging in a rigorous assessment of the appropriateness of a drug and performing a full clinical evaluation, will do little to protect individuals from harm.

The claim that overpromotion may undermine a physician's ability to exercise advertising exception where an end-user's "reasonable reliance" on advertisements, whether or not viewed by the end-user, is supposed to wipe out any responsibility of the physician to make a prudent determination of the appropriateness of the drug. See, e.g. William B. Hirsch and Fabrice N. Vincent, 18 No. 1 Prod. Liab. L. & Strategy 4 (1999) ("drug manufacturers should be prepared to compensate those who suffer injuries as a result of reasonable reliance on drug advertisements that fail to adequately warn of product risks and drug alternatives").

¹⁷²See, e.g. Noah, *supra* note 30, at 172 ("the advertising exception seemingly would eliminate the learned intermediary rule even in cases where the plaintiff had not seen or relied on any promotional claims for a particular drug and exerted any pressure on the physician.") But see Tyler and Cooper, *supra* note 118, at 1103 for an attempt at a solution to this problem, where they propose that loss be apportioned to manufacturers according to their contribution to risk. The case-by-case administration of such a rule would still leave the problem of unsettled expectations. See *infra* notes 163-169 and surrounding text for a discussion of this problem.

appropriate judgment in the prescribing decision is compelling in the context of manufacturer promotion schemes directed at physicians but not where the advertisements are directed at consumers. Courts have quite appropriately recognized that overpromotion or false assurances to the learned intermediary may dilute the effectiveness of warnings and render them inadequate, insofar as such marketing may cause the ultimate arbiter of the prescribing decision to downplay dangers associated with the drug.¹⁷³ The notion that overpromotion may disable the learned intermediary and distort his or her reasoned judgment has much less bite in the DTC advertising context, however. While DTC advertisement may increase patient demand for a prescription drug, it ultimately does not (a) impact the medical decision of whether to prescribe in light of an individual patient's medical history¹⁷⁴ or (b) undermine a physician's ability to understand prescription drug warnings. Because courts, regulatory authorities and professional associations so closely monitor the manner in which prescription drugs

¹⁷³Courts have responded by holding that over-promotion to medical professionals may nullify marginally adequate warnings provided by the manufacturer. See, e.g. Stephens v. Parke-Davis & Co., 507 P.2d 653 (1973); Love v. Wolf, 38 Cal. Rptr. 183 (Cal. Ct. App. 1964) (where the court held that the duty to warn end-users shifted to the manufacturer, because the manufacturer had "watered down its regulations-required warnings and had caused its detail men to promote a wider use of the drug by physicians than proper medical practice justified").

¹⁷⁴This is particularly true where patients circumvent their regular physicians and shop for a physician willing to prescribe a certain medication, either through office visits or on the internet. Recognizing an advertising exception will only reward and shelter such reckless physicians, particularly physicians willing to prescribe a drug over the internet without ever having physically examined the patient. An advertising exception covering such circumstances is not likely to decrease injuries resulting from the use of inappropriate medication, as manufacturer provided warnings would be unlikely to deter consumers who are willing to obtain the drug at all costs even if it requires physician shopping. See Jay B. Spievack, *Direct Ads May Create Liability Dangers*, Nat'l L. J., March 15, 1999 n. 21 ("The fact that the patient and health care provider have freely decided to forgo a physical examination should not somehow make a pharmaceutical manufacturer responsible for their careless act or omission.").

are promoted to physicians to ensure lack of bias and accuracy,¹⁷⁵ physicians remain well equipped to act as learned intermediaries and to respond appropriately to patient pressure even in an age of DTC prescription drug advertising.¹⁷⁶ A more closely tailored and effective response to concerns of DTC advertising-inspired patient pressure for a prescription is a physician notification and educational campaign conducted by the manufacturer.¹⁷⁷ This would alert physicians to a DTC campaign which might increase the frequency of which a certain drug would appear in physician-patient dialogue. Further, it would provide a refresher course for physicians of the side effects and contraindications making prescription unwise, ultimately sharpening the learned intermediary's ability to exercise reasoned judgment with respect to the advertised drug.¹⁷⁸ Such an educational campaign would be responsive to the concern that a physician battles an unknown source of information that has fueled the patient's request¹⁷⁹ and would prepare a physician to educate patients with preconceived expectations about an advertised drug about why that course of treatment may be inappropriate. This preventative approach would be far superior to an advertising exception, insofar as the review provided to learned intermediaries would render injury less likely. An advertising exception, in contrast, is less likely to reduce

¹⁷⁵See Noah, *supra* note 30, at 160.

¹⁷⁶See Allen, *supra* note 152, at 127.

¹⁷⁷See Wendy Borow, CDER Direct-to-Consumer Promotion Public Hearing, Oct. 18, 1995.

¹⁷⁸See *id.*

¹⁷⁹See Hall, *supra* note 19, at 450 (arguing that DTC advertising "undermines the traditional legal rules governing transmission of information to patients" in part because "the doctor must deal with an unknown source of information").

injuries up front; its chief virtue would be to ensure easier recovery for an individual in a tort claim after injury has resulted.

Informed consent critiques of DTC advertising are also more appropriately addressed by measures other than a DTC advertising exception. If the chief concern is that physician warnings of potential side effects may fall on deaf ears in light of positive imagery provided by DTC advertising,¹⁸⁰ it is more effectively addressed by patient package inserts (PPIs) than by altering tort liability standards. PPIs would serve as an informational supplement in disclosing particular warnings that may be useful for patients to counterbalance against promotional claims. They would also serve as an easy-to-understand, written memorialization of the physician's verbal instructions to which end-users may refer back to periodically.¹⁸¹ The PPI summary, abbreviated for clarity and intelligibility's sake, would not supply endusers however with full information necessary to make the prescribing determination because it would contain warnings of only the most serious side effects. It would preserve the learned intermediary's role in working with informed patients to prevent end-user injury, as it would not excuse physicians from exercising sound medical judgment.¹⁸² Provision of

¹⁸⁰See Hirsch and Vincent, *supra* note 171 ("As prescription drug manufacturers market their drugs directly to consumers, the physician's actual ability to deter consumption by effectively communicating product warnings is likely to be eroded."). See also Jeffrey A. Cohen and Janet A. Sullivan, 17 No. 3 *Prod. Liab. L. & Strategy* 1 (1998) ("One could argue, however, that even assuming that the warnings given to the 'learned intermediary' were adequate at the time of sale, the risks conveyed to the patient by the physician, or perceived and weighed by the patient, were diluted by direct advertisements to the consuming public.").

¹⁸¹See Paytash, *supra* note 135, at 1361 ("Verbal warning given by doctors to patients who may be in pain or ill are easily forgotten. Written warnings, in contrast, can be reread and referred to at a later time.").

¹⁸²See *id.* at 1369.

PPIs would not undermine the basis of the learned intermediary rule but rather complement it. In the case of oral contraceptives, where the FDA has long required PPIs, the requirement was implemented with the express intent that it would not relieve physicians from determining whether a drug is appropriate for a particular individual.¹⁸³ The overwhelming number of courts petitioned to recognize an exception to the learned intermediary rule based on the provision of PPIs have ratified this understanding, as they have declined to opportunity to do so.¹⁸⁴ Courts have instead used such occasions to affirm that the learned intermediary rule is fully applicable where prescription drugs contain PPIs.¹⁸⁵

Conclusion

Perez was an unfortunate opinion because it was poorly informed by case

¹⁸³43 Fed. Reg. 4214, 4214-4215 (1978) (contraceptive PPIs instituted were not intended to “affect adversely the standard of civil tort liability which is imposed on drug manufacturers and dispensers” but rather “serv[e] primarily as an informational adjunct to the physician-patient encounter and is intended to reinforce and augment oral information given by the physician to the patient at the time the drug is prescribed”).

¹⁸⁴See, e.g., Martin v. Ortho Pharmaceutical Corp., 661 N.E.2d 352, 355 (Ill. 1996) (“A majority of courts considering the question have held that the FDA regulations concerning contraceptive pharmaceuticals should not serve as a basis to displace or create exceptions to the learned intermediary doctrine...By refusing to abrogate State common law in light of a Federal regulation, these courts have recognized the important policy considerations underlying the learned intermediary doctrine. The doctrine rests on the assumption that prescribing physicians, and not pharmaceutical manufacturers, are in the best position to provide direct warnings to patients concerning the dangers associated with prescription drugs.”); McPherson v. Searle & Co., 775 F. Supp. 417, 424-25 (D.D.C. 1991) (rejecting plaintiff’s contention that “a duty to provide direct and adequate warnings to users of the pill is implicit in the Food and Drug Administrations package insert regulations”). But see *supra* note 49 for rare instances where courts have departed from this approach.

¹⁸⁵See, e.g., Zanzuri v. G.D. Searle & Co., 748 F. Supp. 1511, 1516 (S.D. Fla. 1990) (stating that it is “not persuaded” that FDA regulations should redefine the scope of the cause of action under state tort law); Spychala v. G.D. Searle & Co., 705 F. Supp. 1024 (D. N.J. 1988) (where the court, in commenting on FDA regulations requiring manufacturers to supply brochures with an IUD, noted that “Patient brochures provided by the manufacturer to physicians for distribution to the consumer may aid the physician in communicating with his patient but do not establish the undertaking by the drug manufacturer of a voluntary duty to warn the patient directly. Moreover, to the extent that [such regulations require patient warnings]...it undercuts if not abrogates the learned intermediary rule and should be narrowly construed.”).

precedent and was a fundamentally misguided attempt to protect end-users of prescription drugs from injury. The majority reached a wrong conclusion because it failed to evaluate DTC prescription drug advertising in the context of traditional rationales of the learned intermediary rule. Had the majority not resorted to willful mischaracterization of the rule's premises, it may not have concluded that the consumer rather than the physician is the actor best situated to receive warnings, make individualized determinations, and prevent end-user injury.

An unvarnished view of DTC prescription drug advertising, which takes into account its informational benefits as well as its potential to mislead consumers, does not furnish automatic support for an advertising exception to the learned intermediary rule. Rather, it supports a system where the FDA remains vigilant in taking swift action against those who violate current guidelines. It also supports a system where the FDA is poised to counteract abuses of DTC advertising that arise, such as substantive critiques of downplayed risk information, by fine-tuning its guidance.

Rationales advanced for abandoning the learned intermediary rule in the context of DTC prescription drug advertising fail to persuade that the rule has outlived its usefulness. Managed care and noninterference with the physician-patient relationship arguments are internally weak and a DTC advertising exception will not solve the problems detailed by these rationales. The argument that DTC advertising may hobble the learned intermediary by increasing the load of prescription drug requests that a physician must evaluate is more compelling,

although it does not warrant the extreme solution of an advertising exception. Physicians are not the targets of DTC promotional efforts, so the theory that overpromotion will distort physician judgment and render them unable to refuse inappropriate prescription drug requests remains unsupported. Moreover, the fear that physicians may relax prescribing guidelines in response to an onslaught of requests is more appropriately remedied by physician prenotification of an impending DTC prescription drug advertisement campaign and refresher materials of the complete side effects and contraindications supplied to learned intermediaries. Similarly, informed consent critiques are more effectively addressed by PPIs than by a shift in tort liability from physician to manufacturer. Provision of PPIs would supply interested consumers with detailed information about a drug's side effects but would continue to hold physicians responsible for exercising responsible judgment in the prescribing context.

Ultimately, the premises of the learned intermediary rule remain valid in the context of DTC prescription drug advertising and do not warrant a departure from the rule. Because medical professionals most fully understand side effect warnings and serve as the only party capable of exercising reasoned medical judgment with respect to individualized risks, they remain the party most strategically situated to evaluate information even in an age of DTC prescription drug advertising. The learned intermediary doctrine serves an indispensable function in protecting consumers and is one not capable of being supplanted by an alternative that insulates patients as well from injury. Shifting responsibility from the prescribing physician, who ultimately authorizes receipt of the drug, to the

manufacturer who theoretically may not be capable of providing meaningful and complete warnings to laypersons, would be a poor, if not ineffective, method of ensuring that inappropriate and potentially harmful prescription drugs are not administered to endusers.